

**TERRI DOUGAN and CARLA
RIGSBY, Joint Administratrixes of
The Estate of BRENDA OAKS,
Deceased,**

VS.

MYLAN LABORATORIES, INC. and)
MYLAN TECHNOLOGIES, INC.,)
A wholly-owned subsidiary of)
MYLAN LABORATORIES, INC.,)

Civil Action No. 2:07-CV-151
Judge J. Ronnie Greer
Magistrate Judge Dennis H. Inman
JURY DEMAND

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Mylan Laboratories Inc. and Mylan Technologies Inc., a wholly-owned subsidiary of Mylan Laboratories Inc. ("Mylan"), submits this Memorandum of Law in Support of their Renewed Motion to Dismiss Count IV of Plaintiffs' Amended Complaint in its entirety and with prejudice, and Counts I, II, and III of Plaintiffs' Amended Complaint with prejudice to the extent each is based on warnings associated with the subject product for failure to state a claim upon which relief may be granted.

I. INTRODUCTION

Defendants Mylan Laboratories Inc. and Mylan Technologies Inc., respectfully request that this Court apply the Preemption Preamble to dismiss Count IV of Plaintiffs' Amended Complaint in its entirety and with prejudice, and Counts I, II, and III of Plaintiffs' Amended Complaint with prejudice to the extent each is based on warnings associated with the subject product. Plaintiffs' state law failure to warn claims contained in Counts I, II, III, and IV of Plaintiffs' Amended Complaint are preempted by federal law related to labeling of prescription drugs and, therefore, fail to set forth a claim upon which relief can be granted.

II. PROCEDURAL HISTORY

Plaintiffs commenced this lawsuit by filing a Complaint in the Circuit Court for Hawkins County, Tennessee, at Rogersville, on May 29, 2007. Summons for Mylan was issued on May 29, 2007 and received by the Secretary of State on May 31, 2007. On June 4, 2007, the Secretary of State served the Summons and Complaint on Mylan. On July 2, 2007, Mylan timely removed this action to the United States District Court for the Eastern District of Tennessee, at Greenville, pursuant to 28 U.S.C. §1441 *et seq.* Mylan timely filed a Motion to Dismiss on July 9, 2007. On July 12, 2007, Plaintiffs filed a Motion for Leave to File Amended Complaint. The Court granted Plaintiffs' motion, and Plaintiffs filed their Amended Complaint on July 13, 2007. Plaintiffs' Amended Complaint cured the statutory deficiency addressed in Mylan's previous Motion to Dismiss, but failed to cure the remaining deficiencies. As such, Mylan re-instates its previously filed Motion to Dismiss as to those deficiencies.

III. STATEMENT OF FACTS

This is an action for damages allegedly sustained by the Plaintiffs as a result of Plaintiffs' decedent's use of the prescription drug Fentanyl Transdermal Systems (hereinafter referred to as "FTS") See Amended Complaint filed by Plaintiffs on July 13, 2007 in the United States District Court for the Eastern District of Tennessee attached hereto as Exhibit A (hereinafter referred to as "Amended Complaint"). Plaintiffs seek compensatory and other damages for harm allegedly resulting from the decedent's use of FTS. See Amended Complaint, "WHEREFORE" clause following ¶ 48.

Plaintiffs claim that the decedent used FTS that had been prescribed by her physician on or before May 29, 2006 and subsequently died. See Amended Complaint at ¶¶ 13, 16. Plaintiffs further claim that decedent "received an overdose of the opioid fentanyl and died" as a result of using the defective FTS product. See Amended Complaint at ¶ 16. Mylan expressly denies Plaintiffs' allegations.

Plaintiffs assert four counts against Mylan. Plaintiffs' claims consist of: (i) strict products liability, (ii) negligence, (iii) breach of implied warranty, and (iv) failure to warn. Mylan denies that any of its actions pertaining to the FTS product in any way caused or contributed to Plaintiffs' alleged injuries. As such, Plaintiffs' claims are not sustainable against Mylan.

IV. ARGUMENT

A. STANDARD OF REVIEW

Pursuant to Fed.R.Civ.P. 12(b)(6), a motion to dismiss for failure to state a claim should not be granted "unless it appears beyond a doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief." Conley v. Gibson, 355

U.S. 41, 45-46 (1957). All well-pleaded allegations must be taken as true and be construed most favorably toward the non-movant. Trzebuckowski v. City of Cleveland, 319 F.3d 853, 855 (6th Cir.2003). While a court may not grant a Rule 12(b)(6) motion based on disbelief of a complaint's factual allegations, Lawler v. Marshall, 898 F.2d 1196, 1199 (6th Cir.1990), the court “need not accept as true legal conclusions or unwarranted factual inferences.” Morgan v. Church's Fried Chicken, 829 F.2d 10, 12 (6th Cir.1987). The Sixth Circuit has made it clear that despite the liberal system of notice pleading, “the essential elements of a plaintiff's claim must be alleged in more than vague and conclusory terms” if such a claim is to survive a Rule 12(b)(6) motion. NicSand, Inc. v. 3M Co., 457 F.3d 534, 541 (6th Cir.2006) (internal citations removed). A complaint must contain either direct or inferential allegations with respect to all material elements necessary to sustain a recovery under some viable legal theory. Weiner v. Klais and Co., Inc., 108 F.3d 86, 88 (6th Cir.1997). Consequently, a complaint will not be dismissed pursuant to Rule 12(b)(6) unless there is no law to support the claims made, the facts alleged are insufficient to state a claim, or there is an insurmountable bar on the face of the complaint. As set forth more fully below, application of these standards to the Plaintiffs’ Amended Complaint in this case warrants dismissal of Count IV of Plaintiffs’ Amended Complaint in its entirety and with prejudice, and Counts I, II, and III of Plaintiffs’ Amended Complaint with prejudice to the extent each is based on warnings associated with the subject product.

B. PLAINTIFFS' FAILURE TO WARN CLAIMS FAIL AS A MATTER OF LAW AS SUCH CLAIMS ARE PREEMPTED BY FEDERAL REGULATION

Plaintiffs claim that the decedent used FTS that had been *prescribed* by her physician on or before May 29, 2006 and subsequently died. See Amended Complaint at ¶¶ 13, 16. Although Plaintiffs do not specifically allege that FTS and its labeling are/were subject to the Food and Drug Administration's ("FDA") review and approval, it is well established that all *prescription* drugs and medications are subject to such review under the Federal Food, Drug and Cosmetic Act.

The congressionally passed Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a) gives the FDA control over the regulation of the prescription drug industry. Under said Act, the FDA is charged with making important judgments regarding consumer safety, including what drugs may or may not enter the marketplace, as well as what warnings and instructions should appear on the approved drugs' labeling.

Pursuant to the FDCA, the FDA is obligated to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Encompassed within such products are prescription drugs intended for human consumption. *Id.* § 393(b)(2)(B). The powers to (1) approve proposed warning labels to ensure that drugs are safe and effective, See *Id.* § 355, and (2) institute enforcement actions against manufacturers for issuing false or misleading labels, See *Id.* § 352, are included within the FDA's delegated authority. Since Plaintiffs' own representations indicate that the drug at issue, FTS, was received via a prescription, it necessarily follows

that the FDA approved FTS as safe to enter the marketplace, and reviewed and approved all warnings and instructions comprised in its labeling.

Since FTS is a prescription medication subject to the FDA's review and approval, Plaintiffs' failure to warn claims against Mylan are preempted by the FDA's intent to regulate the area of prescription drug labeling. Over a year ago, the FDA enacted a rule modifying its prescription drug and biological product labeling requirements, accompanied by a preamble known as the "Preemption Preamble"¹. The preamble to the rule was given such a moniker because the FDA clearly and succinctly stated its intent to preempt certain state law claims based on federal drug and biological product labeling requirements.² The application of the Preemption Preamble causes failure to warn claims grounded in state law to be preempted when labeling is done in accordance with FDA regulations.

In the Preemption Preamble, the FDA made its position related to the labeling of prescription drugs unequivocally clear. Specifically, the FDA stated that "FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary state law." See 71 Fed.Reg at 3934. Additionally, in the Preemption Preamble, the FDA addressed why state law claims interfere with the federal objectives of drug labeling, and are therefore preempted.

First, The FDA stated that state law inadequate warning claims can result in manufacturers exaggerating the risks of a drug to avoid liability, and, as a result, discourage a drug's beneficial use. Id. Second, The FDA takes the position that state law warning claims can lead to over-warning. Id. According to the FDA, over-warning can

¹ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922-97 (Jan. 24, 2006) (effective date June 30, 2006)

² Preemption Preamble, at 3934.

also have a negative impact on patient safety and public health. Id. “[L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to ‘lose its significance.’” Id. In essence, the FDA has taken the position that a product with too many warnings can result in the significant contraindications and side effects being overshadowed.

Finally, the FDA believes that state law inadequate warning claims undermine the “FDA’s statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.” See 71 Fed.Reg. at 3934. Under the state tort systems, lay juries get to second-guess the FDA’s careful assessment of the benefits versus the risks of a specific drug to the general public and drive manufacturers to propose “defensive labeling” to avoid state liability. Id. Therefore, “FDA interprets the act to establish both a ‘floor’ and a ‘ceiling,’ such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading.” Id.; See also Sykes v. Glaxo-SmithKline, 484 F.Supp.2d 289, 308-309 (E.D.Pa. 2007).

The FDA, through the Preemption Preamble, has carefully considered its position and made its determination regarding the labeling of prescription drugs. Accordingly, it is the duty of the courts to grant the FDA’s position deference when ruling on state law failure to warn claims³. The Supreme Court has pronounced that an agency’s

³ Tennessee already acknowledges that deference should be paid to industry standards by creating a rebuttable presumption of safety where a manufacturer complies with industry standards or regulations existing at the time the product at issue was manufactured. See Tenn. Code Ann. §29-28-104 (2000). Unlike most industry standards that create minimum thresholds of care, however, the FDA standard governing prescription drug labeling expressly states that it sets forth both the minimum and maximum thresholds of care, thereby preempting any challenges to warnings that comply with the standard. See 71 Fed.Reg. at 3934. The Preemption Preamble is more akin to the standards governing medical devices, which the Tennessee courts have already recognized preempt state law challenges. See Hughes v. Cook, M.D., et. al, 452 F.Supp.2d 832 (W.D.Tenn. 2006)

interpretation of the statutes and regulations it administers is entitled to deference when Congress has not made its intent known. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) (holding that it has been “long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer”).

In the context of preemption, the Supreme Court has held that the FDA’s position on the preemptive scope of its regulatory authority is dispositive as long as Congress does not clearly express its intent or other developments do not occur that reveal a change in the agency’s position. See Hillsborough County v. Automated Labs, Inc., 471 U.S. 707, 714 (1985). Since the pronouncement of the Preemption Preamble, multiple jurisdictions have analyzed and applied it to dismiss failure to warn claims. To date, this jurisdiction has not ruled on the Preemption Preamble. Notwithstanding this jurisdiction’s silence on the issue to date, there can be no doubt that the Preemption Preamble mandates that state failure to warn claims be dismissed.

California and Pennsylvania are among the jurisdictions that have considered and ruled in favor of the Preemption Preamble. Although these jurisdictions’ findings are not binding on this court, the well reasoned opinions of the jurists in those jurisdictions serves as guidance for addressing the issue.

For instance, in In re: Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, 2006 WL 2374742 at *4-*12 (N.D. Cal. August 16, 2006), a class of users of the drug Celebrex, a non-steroidal anti-inflammatory drug (“NSAID”), brought suit against its manufacturers. Pfizer developed Celebrex, an NSAID known as a COX-2 inhibitor, with the goal that it would cause fewer gastrointestinal side effects than

traditional NSAIDs. Id. The labels at issue in In re: Bextra contained warnings against gastrointestinal problems and aggravated hypertension. Id. In May 1999, the FDA revised the label so that it reported certain cardiovascular adverse events in less than two percent of the studied patients, but the label did not otherwise warn of cardiovascular risks. Id. Additionally, in 2005, the FDA also required the Celebrex label to include gastrointestinal warnings. Id.

In reaching its conclusion that the cardiovascular claims were preempted, the court gave great deference to the FDA's position. The court recognized that it is required to give weight to an agency's view of preemption. Id. at 7. The court further observed that the Supreme Court has recognized that an agency's view of the preemptive effect of its regulations may change over time as the agency gains more experience with the interrelationship between its regulations and state laws. In re: Bextra, 2006 WL 2374742 at *4-*12. The court stressed that the plaintiff's claim attempted to "require Pfizer to include in its Celebrex promotion a warning which the FDA has considered and found to be scientifically unsubstantiated." Id. The court reasoned that "the FDA is in a better position than the Court to determine whether state laws that encourage manufacturers to propose defense labels upset the FDA's careful balance of statutory objectives." Id. at 9.

Similarly, in Conte v. Wyeth, Inc., 2006 WL 2692469 (Cal. Superior 2006) (not reported), the California Superior Court recognized the In re: Bextra holding and followed suit. In Conte, the plaintiff alleged that she was overexposed to metoclopramide as a result of the manufacturer's misleading or materially incomplete information related to the drug's side effects. Id. at 1. Specifically, plaintiff brought claims for strict liability, negligence, negligence per se, breach of express warranties and

breach of implied warranties. The defendant manufacturers challenged the failure to warn components contained in each claim on the grounds that they were effectively preempted by the federal laws governing labeling of prescription drugs.

In granting summary judgment on each of the aforementioned causes of action, the California Superior Court considered the opinion rendered in In re: Bextra. In that case, Judge Breyer recognized that deference was warranted because “Congress has delegated to the FDA authority to implement the FDCA; ‘the subject matter is technical; and the relevant history and background are complex and extensive.’ The FDA is thus ‘likely to have a thorough understanding of its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements.” In re: Bextra, 2006 WL 2374742 at *6.

California is not the only jurisdiction to embrace the FDA’s position on preemption. For example, in Colacicco v. Apotex, 432 F. Supp. 2d 514 (E.D. Pa. 2006), the District Court held that failure to warn claims against two pharmaceutical companies were preempted by the FDA’s authority over drug labeling. Id. In that case, plaintiffs filed suit against GlaxoSmithKline, the manufacturer of the antidepressant Paxil, and also against Apotex, the manufacturer of the generic equivalent of Paxil. Plaintiffs alleged that, despite FDA approval of the label, defendants had a duty to warn of the increased risk of suicide in those taking the drug. Id.

The defendant manufacturers moved to dismiss on grounds that FDA regulation occupied the territory of drug labeling to the extent that there is no room for regulation by the states, a theory known as “field preemption.” In reaching its conclusion, the court relied heavily on the FDA’s amicus brief in which the agency stated its belief that any

warning of a connection between Paxil and suicide would be false and misleading. Moreover, the court relied on the FDA's position that its Preamble (although not yet in effect) expressly preempted state law claims. The court observed that great deference must be afforded to the FDA in interpreting the scope of its own rules and regulations. Id. at 529. Consequently, plaintiffs' claims were dismissed based on a retroactive application of the Preemption Preamble.

The Eastern District of Pennsylvania again addressed the Preemption Preamble in Sykes v. Glaxo-SmithKline, 484 F.Supp.2d 289 (E.D.Pa. 2007) and issued an opinion consistent with its holding in Colacicco. In Sykes, the plaintiffs brought suit against multiple pharmaceutical manufacturers for injuries sustained by their eleven-year-old son. The plaintiffs' alleged harm resulting from exposure to immune globulin in utero, as well as from exposure to multiple vaccines over the child's first three years of life. Both the immune globulin and vaccines were manufactured by the named defendants. Id. at 292.

Again, the pharmaceutical defendants defended the actions, *inter alia*, on the grounds that the Preemption Preamble preempted all state law failure to warn claims. The judge in this case issued one of the most well reasoned opinions to date on the issue. In considering whether or not the claims were preempted, the district judge first considered the language of the preamble itself. As we have noted above, the judge pointed out that the Preemption Preamble specifically states that the "FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law. Id. at 309.

The Sykes judge did not simply rest on the assertion made by the FDA that its labeling requirements governed. Rather, the judge next addressed the reasoning given by the FDA for its position. Specifically, the court considered the statements that the FDA detailed in the Preemption Preamble and the role the agency plays in approving and updating a drug label:

FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based ... on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. 355(d)).... The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate. 71 Fed.Reg. at 3934.

The court concluded that since the FDA's approval of the labeling for all of the products involved, plaintiffs' failure to warn claims against the products' manufacturers were preempted as the FDA "fulfilled its statutory role as the expert federal agency responsible for evaluating and regulating drugs." Sykes, 484 F.Supp.2d at 312.

The California and Pennsylvania cases cited above provide persuasive guidance to this court. In fact, Conte has particular relevance to the case at issue before this Court.

In Conte, the Preemption Preamble was held to negate claims for not only counts expressly titled "failure to warn", but also counts that alleged that the defendant's liability

arose as a result of failing to give warnings. As a result, the preemptive power of the Preemption Preamble was extended to negligence, negligence per se, breach of express warranties and breach of implied warranties.

In the instant matter, the Plaintiffs have four claims that should be dismissed, albeit some in part, as a result of preemption: (i.) strict liability, (ii.) negligence, (iii.) breach of implied warranty and (iv.) failure to warn. In their strict liability claim, Plaintiffs allege that the decedent died as a direct result of the defective warnings associated with Mylan's FTS product. See Amended Complaint at ¶ 29. In addition to this claim, Plaintiffs allege that Mylan should be liable for negligence due to its failure to "exercise reasonable care in designing, creating, manufacturing, testing, *labeling*, packaging, supplying, marketing, selling, advertising, *warning* and otherwise distributing and placing in the stream of commerce fentanyl patches, including the fentanyl patches at issue in this lawsuit." See Amended Complaint at ¶ 32 (*emphasis added*). Plaintiffs further allege that the FTS product was not safe for its intended purpose, based, in part, on the allegedly inadequate warnings associated with the drug. See Amended Complaint at ¶¶ 39-43. Lastly, Plaintiffs expressly allege a failure to warn count against Mylan. In said count, Plaintiffs claim that Mylan failed to advise the decedent and other users of defects in the FTS drug. See Amended Complaint at ¶ 47.

Each of the aforementioned claims relate, in part or in total, to the adequacy of the warnings accompanying the FTS product. Since any and all warnings associated with the FTS product were mandated, reviewed, revised and ultimately approved by the FDA, Plaintiffs' state law claims challenging the sufficiency of said warnings are preempted⁴.

⁴ Plaintiffs fail to assert any allegations, or set forth any facts, evidencing Mylan's failure to comply with FDA regulations and requirements.

In accordance with the rationale employed by the In re:Bextra and Conte courts, this Court should dismiss Counts I, II, and III of Plaintiffs' Amended Complaint with prejudice to the extent each is based on warnings associated with the subject product, and dismiss Count IV of the Amended Complaint in its entirety with prejudice, since the entire count is based on the adequacy of warnings associated with the subject product.

In Conte, the Superior Court expressly rejected the plaintiff's claims containing identical or very similar language to Plaintiffs' claims in the instant matter. Although Plaintiffs have attempted to package their claims under the headings of strict liability, negligence and breach of implied warranty, the fact remains that these claims simply and clearly assert challenges to the adequacy of warnings associated with FTS, similar to those asserted in Plaintiffs' failure to warn count.

In conclusion, the FTS label in this case was formulated in strict accordance with the labeling requirements set forth by the FDA. This is evidenced by the fact that FTS was ultimately approved by the FDA for entrance into the stream of commerce. The FDA fulfilled its statutory role as the expert federal agency responsible for evaluating and regulating drugs when it evaluated, regulated, and ultimately *approved* FTS. As such, the Preemption Preamble applies here and preempts any conflicting state law, mandating dismissal of Plaintiffs' failure to warn claims. The warnings accompanying FTS should be deemed valid under the Preemption Preamble, and any claims challenging the adequacy of such warnings contained in Plaintiffs' Amended Complaint should be dismissed with prejudice.

V. CONCLUSION

Based on the foregoing, Defendants Mylan Laboratories Inc. and Mylan Technologies Inc., respectfully request that this Court apply the Preemption Preamble to dismiss Count IV of Plaintiffs' Amended Complaint in its entirety and with prejudice, and Counts I, II, and III of Plaintiffs' Amended Complaint with prejudice to the extent each is based on warnings associated with the subject product.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 26, 2007, I electronically filed the foregoing DEFENDANTS MYLAN LABORATORIES INC.'S AND MYLAN TECHNOLOGIES INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS with the Clerk of this Court using the CM/ECF system, which will send notification of such filing to the following opposing counsel of record:

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And I hereby certify that a copy of the foregoing was served on the following non- CM/ECF participants by United States mail, postage prepaid, addressed as follows:

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s/ James M. Doran, Jr.